



6760 '99 DEC -6 AM 13

Thomas T. Lee, M.D.

December 1, 1999

KENT R. DUFFY, M.D.
EZRIEL E. KORNEL, M.D., F.A.C.S.
THOMAS LANSSEN, M.D., F.A.C.S.
JACK STERN, M.D., Ph.D., F.A.C.S.

TO: Food and Drug Administration

FROM: Thomas T. Lee, MD
222 Westchester Avenue, Suite #202
White Plains, NY 10604
(914)948-6688

TEL: (914) 948 6688

FAX: (914)948 0351

222 WESTCHESTER AVENUE
SUITE 202
WHITE PLAINS, NY 10604

136 E. 57th ST., SUITE 600
NEW YORK, NY 10022

RE: allograft bone and Docket No. 97N-484S

I oppose further regulation of bone graft materials as outlined by the FDA. FDA's proposed action to further regulate the distribution of bone bank allograft material will severely limit the sources of bone grafts, which are extremely important in the care of my patients: "By excessive regulation as proposed by the FDA, patients would receive substandard and delayed surgical treatment. I do not believe this is an acceptable way to deal with the issue on hand. Uniform processing guideline is a more sensible way to proceed."

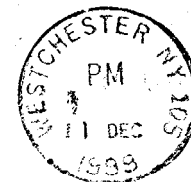
Thank you for your consideration.

97N-484S

SPECIALIZING IN SURGERY OF THE SPINE AND NERVOUS SYSTEM

C 16

NEUROSURGEONS OF NEW YORK
222 WESTCHESTER AVENUE
SUITE 202
WHITE PLAINS, N.Y. 10604-2906



Document Management Branch (HFA-305)
FDA
5630 Fishers Lane, Rm 1061
Rockville MD 20852

